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OSTOMY SYSTEM

Technical field

The present invention relates to ostomy systems for bodily waste. More particularly, the invention concerns an improved filter arrangement of such a system for preventing liquids and solid particles from passing from a drainage bag of the system to the surrounding of the drainage bag.

Background of the invention

A large number of ostomy bags for receiving bodily waste from colostomy or ileostomy patients have been proposed in the prior art.

European patent application No. 0 607 028 discloses an ostomy bag for holding body waste comprising an envelope formed of flexible plastic sheet material defining a waste collection chamber. The envelope defines a gas outlet proximate a top end portion of the envelope and spaced from a waste inlet opening of the envelope. A deodorizing filter is joined to the envelope in alignment with the gas outlet means for deodorizing gaseous waste material before the gaseous waste exits from the bag through the gas outlet. In the envelope, there is provided means for protecting the deodorizing filter from contact by semi-liquid waste material, and for permitting the flow of gaseous waste, and for obstructing the flow of semi-liquid waste, the protection means comprising a porous protection film preceding the deodorizing filter. The protection means further comprises open cell foam material preceding the porous protection film such that the gaseous waste must pass through the open cell foam material, and through the porous protection film before it passes through the filter. It is thereby sought to provide a multi-stage filter system that prevents semi-liquid waste material from contaminating a deodorizing element but does not inhibit evacuation of gaseous waste through the deodorizing filter.

US patent No. 6,135,976 discloses an ostomy appliance comprising a front wall and a rear wall of flexible material, the rear wall having an opening into the bag by which waste material can enter the bag. One of the walls has one or more vents through which gas may escape from the bag. The appliance has a filter covering the vent, the filter comprising an elongated, substantially flat filter body of a porous filter material interposed between gas and liquid impervious walls which are sealed to the body along its longitudinal side edges. Gas inlet and outlet opening are provided in communication with the filter material adjacent to its respective longitudinal end regions. The gas and liquid impervious walls are sealed to the upper end lower surfaces of the filter body. In use, gas flows longitudinally through the filter

from the inlet opening to the outlet opening. The inlet opening is covered with a microporous hydrophobic and oleophobic membrane, and the foam material is placed between the front wall and the rear wall and covers the inlet opening of the vent. The appliance of US 6,135,986 thereby shows improved resistance against wetting and blocking of the filter.

It has been found that porous filter arrangements as those suggested in the prior art may tend to clog due to faeces being deposited therein, whereby the drainage bags, including the filters, may have to be replaced at relatively short intervals. It is therefore and object of preferred embodiments of the present invention to provide an ostomy system with a filter arrangement which does not clog as rapidly as the prior art filter arrangements.

Summary of the invention

In a first aspect the invention thus provides an ostomy system for receiving bodily waste, comprising:

a drainage bag;

at least one filter comprising a foam for preventing liquid and solid particles from passing from the drainage bag to its surroundings, the foam defining a passageway for releasing flatus gasses from the drainage bag to its surroundings;

characterised in that

at least a portion of the foam is arranged at a folding line defined by the drainage bag during use thereof.

As at least a portion of the foam is arranged at the folding line, faeces may be expelled by the foam as pores of the foam are repetitively opened and closed when the drainage bag is folded and unfolded in the area of the foam. Thus, a user of the ostomy system may cause pumping of liquid and solid particles, in particular faeces, out of the foam by folding the bag, such folding occurring naturally when the user seats or lies down, rises after having been seated or having been to bed, walks, bends etc. In the present context, the term folding should be understood as any bending or folding resulting in a compression of the foam. In order to ensure an efficient pumping effect for expelling faeces form the filter, the folding line may intersect the filter at an inlet thereof or at a distance from the filter inlet, for example 5 – 20 mm from the filter inlet. Expelling of faeces may occur as a consequence of the cross-sectional area of the foam inlet being smaller than the cross-sectional area in the interior foam during folding. When the bag is unfolded, the cross-sectional area of the filter inlet increases, resulting in a pumping or sucking effect which draws faeces deposits from inside the foam towards the inlet.

In an envisaged use of the ostomy system according to the invention, the user may define one more folding lines by folding the bag and/or filter prior to attaching the bag to her or his stoma. For example, instructions may be provide along with the ostomy system, instructing the user to pre-fold the bag prior to attaching it. Alternatively, the bag may be pre-folded, i.e. folded prior to delivery thereof to the user.

In the present context, the term foam should be understood as a porous material, through which flatus gasses may travel, but which serves as at least a partial barrier to liquid and solid particles. Examples of such porous materials are disclosed in prior art documents EP 0 607 028 and US 6,135,986. The foam may have a deodorizing effect which may be achieved by embedding an activated carbon in the foam.

Normally, an ostomy system is not tailored to an individual user, and accordingly the exact position of the folding line may not always be predictable at the stage of designing the ostomy system. Therefore, in one embodiment, the ostomy system comprises a plurality of filters, at least a portion of at least one of the filters being arranged at a folding line defined by the drainage bag during use thereof. Preferably, the plurality of filters are arranged at different positions, so that at least one of the filters is ensured to be in the vicinity of that folding line which is ultimately defined by the user's use of the ostomy system.

The ostomy system preferably comprises a coupling system for securing the bag in relation to a stoma of a patient, the coupling system defining an orifice to enable bodily waste to be received by the drainage bag. The drainage bag may be a biodegradable inner bag surrounded by an outer bag which may be disposed of with household refuse, the filter being thus provided in the inner bag or in the coupling system, so as to prevent liquid and solid particles from passing from the inner bag to the outer bag. The coupling system may serve to secure the inner as well as the outer bag in relation to the patient's stoma.

In case the filter has no deodorizing effect, the outer bag is preferably made from a material which is essentially impermeable to flatus gasses, the outer bag comprising on outlet with a flatus filter for releasing flatus gasses from the outer bag. The flatus filter may be a conventional activated carbon filter.

In one embodiment, the drainage bag is impermeable to flatus gasses, in which case flatus gasses may only escape from the inner bag to its surroundings via the coupling system. The impermeability of the drainage bag may preferably be achieved by a material for the inner bag which is impermeable to flatus gasses. Accordingly, once the drainage bag has been detached from the coupling system, flatus gasses may only escape from the drainage bag through a faeces inlet opening thereof, through which faeces has entered the bag. As the bag

is impermeable to flatus gasses, no such gasses escape via the walls of the bag. A user may seal the faeces inlet opening of the bag prior to disposing the bag into a WC bowl, such sealing being, e.g., achieved by the user tying a knot in the inner bag or simply by folding and/or pressing portions of the wall material in the area of the faeces inlet opening. It may hence be achieved that less obnoxious smells diffuse out of the drainage bag during the process of disposing the bag than if the drainage bag is made from a gas permeable material.

The foam of the filter may comprise a gas permeable membrane, such as a hydrophobic gas permeable membrane, to provide a further barrier to liquid and solid particles. It will be understood that the actual choice of foam and membrane is a matter of selecting among commercially available products with the required gas permeability and particle/liquid impermeability characteristics. While liquid may normally penetrate into the foam, though not all the way through the foam, provided the foam is sufficiently dense and/or sufficiently thick, the membrane is normally liquid proof. Thus, it is usually desirable to include a membrane in embodiments, in which the coupling system is to withstand large quantities of liquid, or in which the travelling distance through the foam is so small that a risk of liquid penetrating through the foam exists.

To ensure that flatus gasses travel a predetermined minimum distance within the foam, the foam may comprise means for forcing the flow of flatus gasses in the barrier along a predetermined flow path. For example, there may be provided a sheet of a plastics material, e.g. PVC, in the foam, the sheet preventing flatus gasses from being conveyed along the shortest, i.e. straight-line route from the inlet to the foam to the outlet thereof. The sheet may e.g. extend along a substantial part of the periphery of the coupling, such as for example along 1/2 to 5/6 of the periphery. Alternatively, there may be provided a junction, e.g. a welding, at which an outer and an inner flange of the coupling system, between which there is provided the foam, are joined, whereby flatus gasses in the foam are prevented from flowing across the junction.

In case of a biodegradable drainage bag, the material of the bag may be such that the bag essentially maintains its physical integrity upon immersion in water. More specifically, the structure may be such that the bag does not loose its buoyancy immediately upon immersion in water or shortly thereafter. Preferably, the material of the bag should be such that it essentially maintains its physical integrity upon immersion in water at 25°C for at least 36 hours, more preferably for at least 48 hours. Most preferably, the bag maintains its physical integrity at a purifying plant or in a septic tank for at least 1 week, such as for 1-4 weeks. This has several advantages. Firstly, it facilitates a user's handling of a used bag to be flushed away, as the user will not wait for what may appear as an inconveniently long time from placing a used drainage bag in a WC bowl until the bag has lost its buoyancy, at which

time the user normally decides to flush the bag away. Once the user has become used to a bag which does not become less buoyant upon immersion in a WC bowl, he or she will not wait at the WC bowl for the bag to sink, and accordingly the user needs to spend less time at the WC bowl. Secondly, as the drainage bag maintains its physical integrity for an extended period of time, it does not dissolve before reaching a purification plant together with the sewage which conveys the bag, and accordingly it may easily be filtered out of the sewage in a water purification process.

In preferred embodiments of the biodegradable drainage bag, the material of the bag comprises a mix of starch, such as maize or potato starch, and polyester, such as synthetic polyester, such as polycaprolactone. It has been found that such a material combines the qualities of being soft, i.e. providing a low level of rustle noise when worn by a user, flexible, and being capable of maintaining its physical integrity upon immersion in water. For example, the material of the inner bag may comprise 35 – 55%, such as 40-50% by weight of starch and 35 – 55%, such as 40-50% by weight of the synthetic polyester. In one embodiment, the material of the inner bag comprises starch and synthetic polyester in substantially equal ratios. In order to soften the inner bag and to improve wearing comfort, the inner bag may comprise 10% or less by weight of a softener, such as glycerol.

In one embodiment, the inner bag is made from a material of the above composition, the material being essentially insoluble in water. The material may be hygroscopic to such a degree that it absorbs 10-25% by weight of water, such as 15-18%. The water permeability of the material may be between 3000 and 4000 g per m^2 per day, and the biodegradability may be such that 10-20 µm of the material thickness is degraded after 2-3 weeks in still water at 25°C. Preferably, the material of the inner bag fulfils ISO standards for biodegradability.

One suitable material for the bag is the commercially available Mater-Bi NF01U, supplied by Novamont SpA, Novara, Italy.

From the above discussion, it will be appreciated that the present invention also provides a method for expelling faeces from a filter of a drainage bag in an ostomy system, the filter comprising a foam for preventing liquids and solid particles from passing from the drainage bag to its surroundings, the foam further defining a passageway for releasing flatus gasses from the drainage bag to its surroundings and being arranged at a folding line defined by the drainage bag during use thereof, the method comprising expelling faeces from pores of the foam when the foam is folded and unfolded, expelling being caused by repetitive opening and closing of the pores occurring when the drainage bag is folded and unfolded in the area of the foam.

In a further aspect, the invention provides a method of attaching an ostomy system to a user's body, the ostomy system comprising a drainage bag and a filter comprising a foam for preventing liquid and solid particles from passing from the drainage bag to its surroundings, the foam further defining a passageway for releasing flatus gasses from the drainage bag to its surroundings, the method comprising arranging the ostomy system such with respect to the user's body that a folding line defined by the drainage bag during the user's use thereof intersects the filter.

Brief description of the drawings

The invention will now be further described with reference to the drawings, in which:

Figs. 1-3 show three different states of a filter in an ostomy system according to the invention;

Figs. 4A-4C and 5A-5C show different positions of a user of an ostomy system and corresponding states of the filter of the system;

Fig. 6 shows an example of the relative position of a filter arrangement with respect to a folding line of the ostomy system with the filter arranged in a coupling system of the ostomy system;

Fig. 7 shows an example of a different position of the filter.

Detailed description of the drawings

The faeces expelling effect of the filter of the ostomy system according to the present invention is illustrated in Figs. 1-3, in which the filter 100 comprises a foam 102 interposed between sheets 103. In Fig. 1, the filter is curved, for example as a consequence of the user of the ostomy system bending slightly. As a result, air is pressed out of pores of the foam 102, the pores being thereby more closed than in their open state depicted in Fig. 2. As shown in Fig. 2, when the filter is stretched, the pores of the foam are more open than in Fig. 1. In Fig. 3, the filter is again curved, and faeces 104 is expelled from the pores of the foam 102 as a result of the pumping function achieved by repetitive bending (or folding) of the filter.

Fig. 4A illustrates a user 108 of a ostomy system 110 according to the invention, the user being seated. As shown in Fig. 4B, the foam 102 of the filter system 100 is partially

compressed. As the user rises to a standing position as shown in Fig. 5A, the pores of the foam open, and as the user is seated again, faeces 104 is expelled from the foam as illustrated in Fig. 4C in the manner described above in connection with Figs. 1-3. Figs. 5B and 5C illustrate the state of the filter 100 corresponding to the user's positions of Fig. 5A.

As illustrated in Fig. 6, the filter 100 with foam 102 may form part of a coupling system 112 for securing the drainage bag of the ostomy system in relation to the user's body. In the configuration of Fig. 6, the filter arrangement comprises two filter sections, respective inlets 116 and 118 of which are intersected by a folding line 114 of the ostomy system. Accordingly, faeces is expelled from the foam 102 when the drainage bag and/or filter system folds, as described above in connection with Figs. 1-5. The two filter sections depicted in Fig. 6 define flatus gas outlets 120 and 122, through which gas may escape to the surroundings of the drainage bag, e.g. to an outer bag or to the surrounding atmosphere.

In the configuration of Fig. 7, the filter 100 does not form part of the coupling system 124, but is arranged near a border edge of the drainage bag 126. Such a configuration is useful in case the stoma of the user is located so that the folding line of the bag 126 does not intersect the coupling system. It will be appreciated that other positions of the filter 100 are feasible, and that multiple filters may be provided at different locations.

CLAIMS

1. An ostomy system for receiving bodily waste, comprising:

a drainage bag;

at least one filter comprising a foam for preventing liquid and solid particles from passing from the drainage bag to its surroundings, the foam defining a passageway for releasing flatus gasses from the drainage bag to its surroundings;

characterised in that

at least a portion of the foam is arranged at a folding line defined by the drainage bag during use thereof.

2. An ostomy system according to claim 1, wherein the filter defines a filter inlet facing the interior of the drainage bag and a flatus gas outlet facing the surroundings of the bag, and wherein the folding line intersects the filter inlet.

3. An ostomy system according to claim 1, wherein the filter defines a filter inlet facing the interior of the drainage bag and a flatus gas outlet facing the surroundings of the bag, and wherein the folding line intersects the filter at a distance from the filter inlet.

4. An ostomy system according to any of claims 1-3, further comprising a coupling system for securing the bag in relation to a stoma of a patient, the coupling system defining an orifice to enable bodily waste to be received by the drainage bag.

5. An ostomy system according to claim 4, wherein the drainage bag is impermeable to flatus gasses, and wherein the filter is provided in said coupling system.

6. An ostomy system according to claim 4 or 5, wherein said surroundings of the drainage bag is constituted by an outer bag which is secured in relation to the patient's body and in relation to the drainage bag by means of said coupling system.

7. An ostomy system according to claim 6, wherein the outer bag is essentially made from a material which is impermeable to flatus gasses and comprises on outlet with a flatus filter for releasing flatus gasses from the outer bag.

8. An ostomy system according to any of the preceding claims, wherein said passageway further extends through a gas permeable membrane.

9. An ostomy system according to any of the preceding claims, wherein the drainage bag is of a structure which essentially maintains its physical integrity upon immersion in water.

10. An ostomy system according to any of the preceding claims, wherein the coupling system comprises means for forcing the flow of flatus gasses along a predetermined passageway.

11. An ostomy system according to any of the preceding claims, wherein the at least one filter comprises a plurality of filters, at least a portion of at least one of the filters being arranged at a folding line defined by the drainage bag during use thereof.

12. A method for expelling faeces from a filter of a drainage bag in an ostomy system, the filter comprising a foam for preventing liquid and solid particles from passing from the drainage bag to its surroundings, the foam further defining a passageway for releasing flatus gasses from the drainage bag to its surroundings and being arranged at a folding line defined by the drainage bag during use thereof, the method comprising expelling faeces from pores of the foam when the foam is folded and unfolded, expelling being caused by repetitive opening and closing of the pores occurring when the drainage bag is folded and unfolded in the area of the foam.

13. A method of attaching an ostomy system to a user's body, the ostomy system comprising a drainage bag and a filter comprising a foam for preventing liquid and solid particles from passing from the drainage bag to its surroundings, the foam further defining a passageway for releasing flatus gasses from the drainage bag to its surroundings, the method comprising arranging the ostomy system such with respect to the user's body that a folding line defined by the drainage bag during the user's use thereof intersects the filter.

14. A method according to claim 13, wherein the filter defines an inlet opening facing the interior of the drainage bag and a flatus gas outlet facing the surroundings of the drainage bag, and wherein the step of arranging includes arranging the ostomy system such that the folding line intersects the filter at the filter inlet or at a distance from the filter inlet.

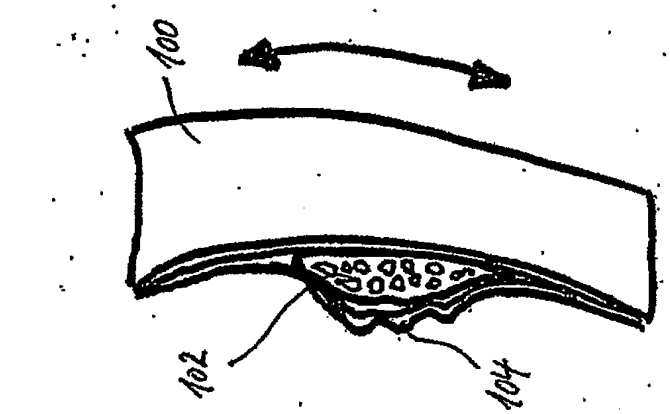

Fig. 3

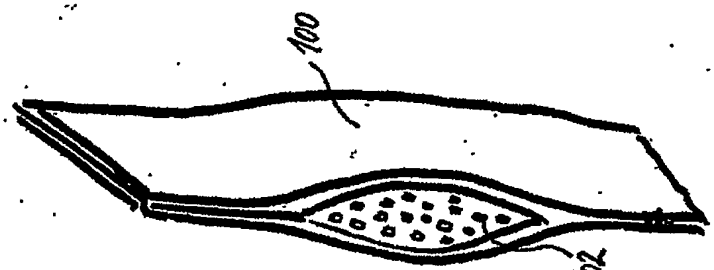

Fig. 2

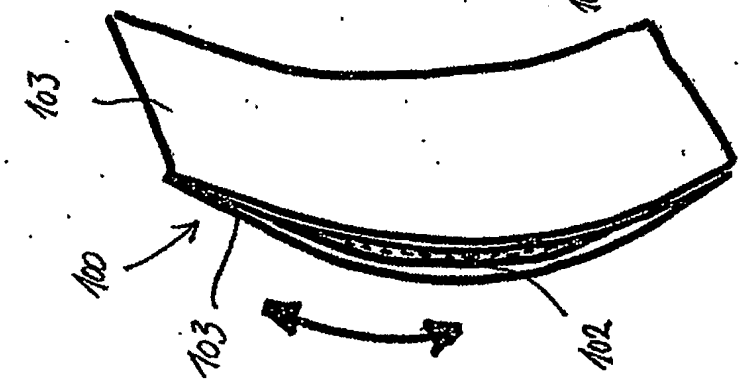

Fig. 1

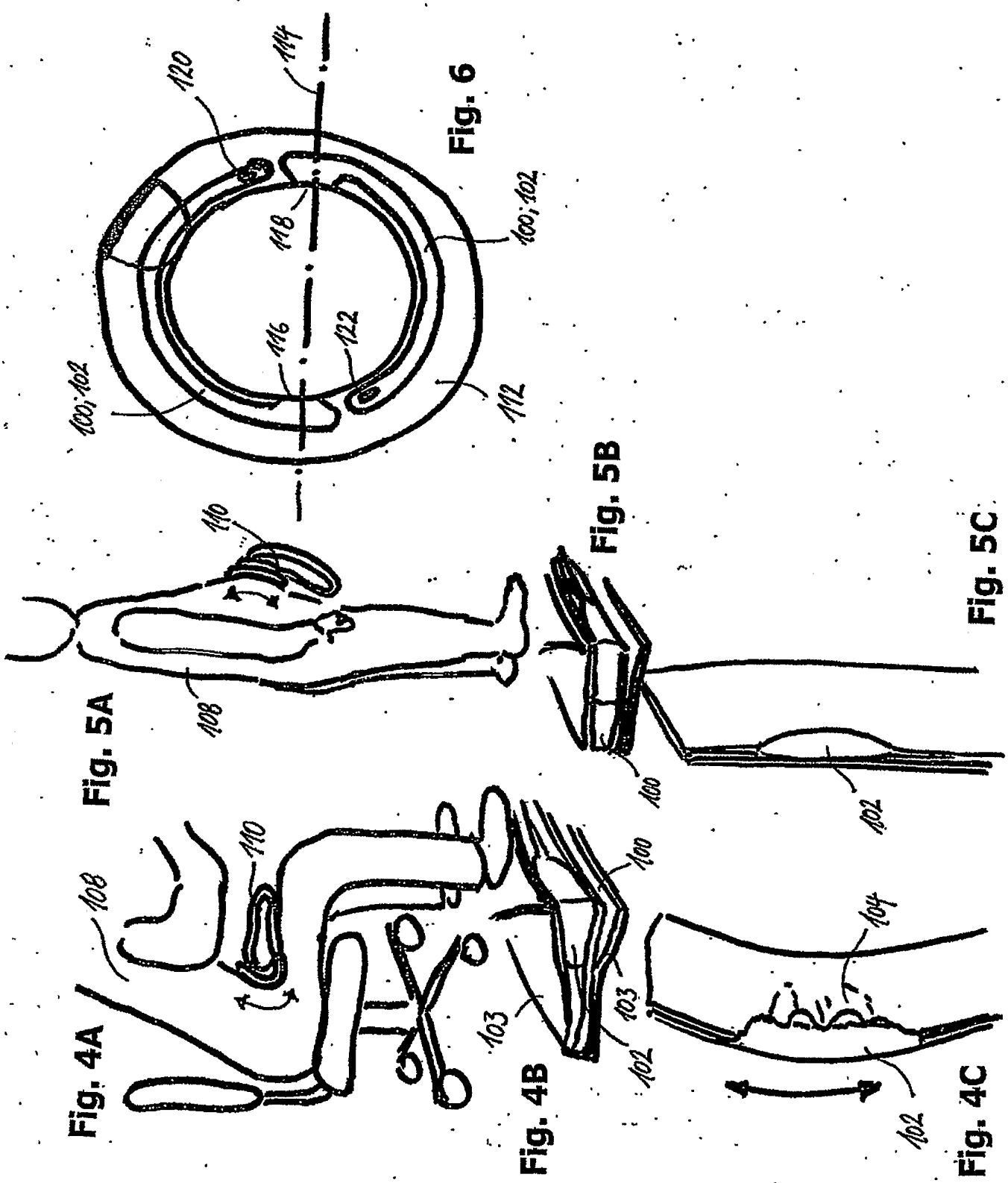
Fig. 4A
108
110
Fig. 4B
103
100
102
Fig. 4C
104
102
Fig. 5A
110
108
Fig. 5B
100
Fig. 5C
102
Fig. 6
120
114
118
116
122
100; 102
112

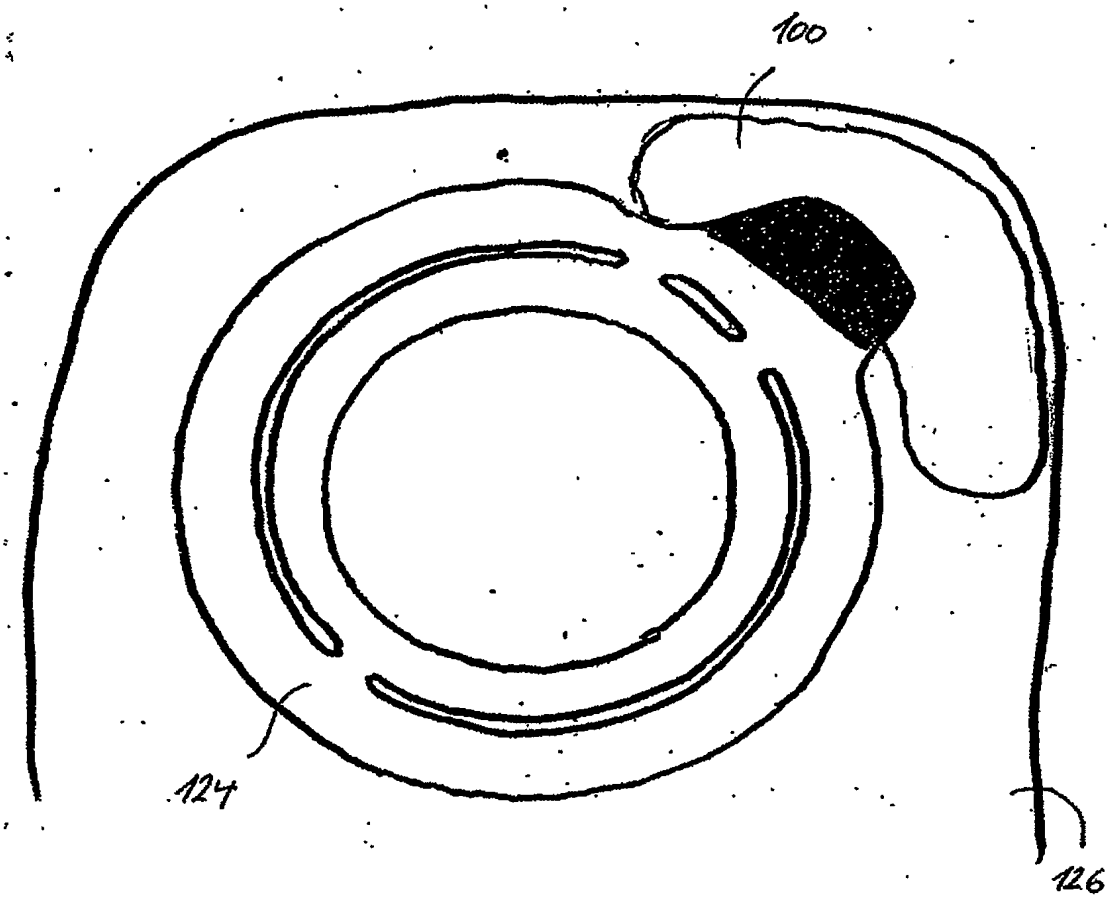

Fig. 7